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Vanney et al.

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[54] **APPARATUS FOR ATTACHMENT OF HEART VALVE HOLDER TO HEART VALVE PROSTHESIS**

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[73] Assignee: **St. Jude Medical, Inc.**, St. Paul, Minn.

[21] Appl. No.: **526,854**

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[51] **Int. Cl.**[6] **A61F 2/24**

[52] **U.S. Cl.** **623/2**; 623/900

[58] **Field of Search** 623/2, 900; 606/1; 206/438

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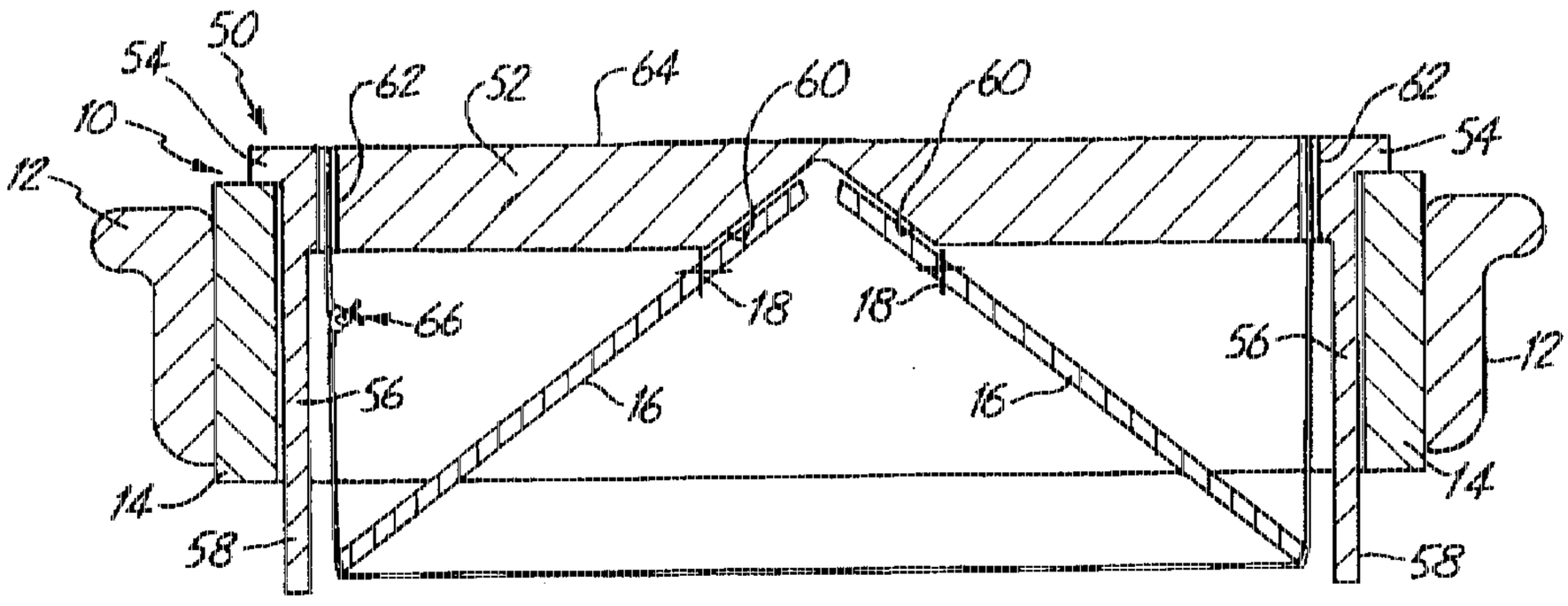
Primary Examiner---Randy C. Shay

Attorney, Agent, or Firm---Hallie A. Finucane, Esq.

[57] **ABSTRACT**

A holder for engaging a heart valve prosthesis during implantation includes a mechanism for attaching the holder to the heart valve prosthesis. The heart valve prosthesis includes a circular valve body having an annulus with a substantially annular aperture therein. At least one movable occluder is carried in the aperture and is movable between an open position and a closed position. The attachment mechanism attaches to the occluder thereby securing the holder to the heart valve prosthesis.

3 Claims, 6 Drawing Sheets



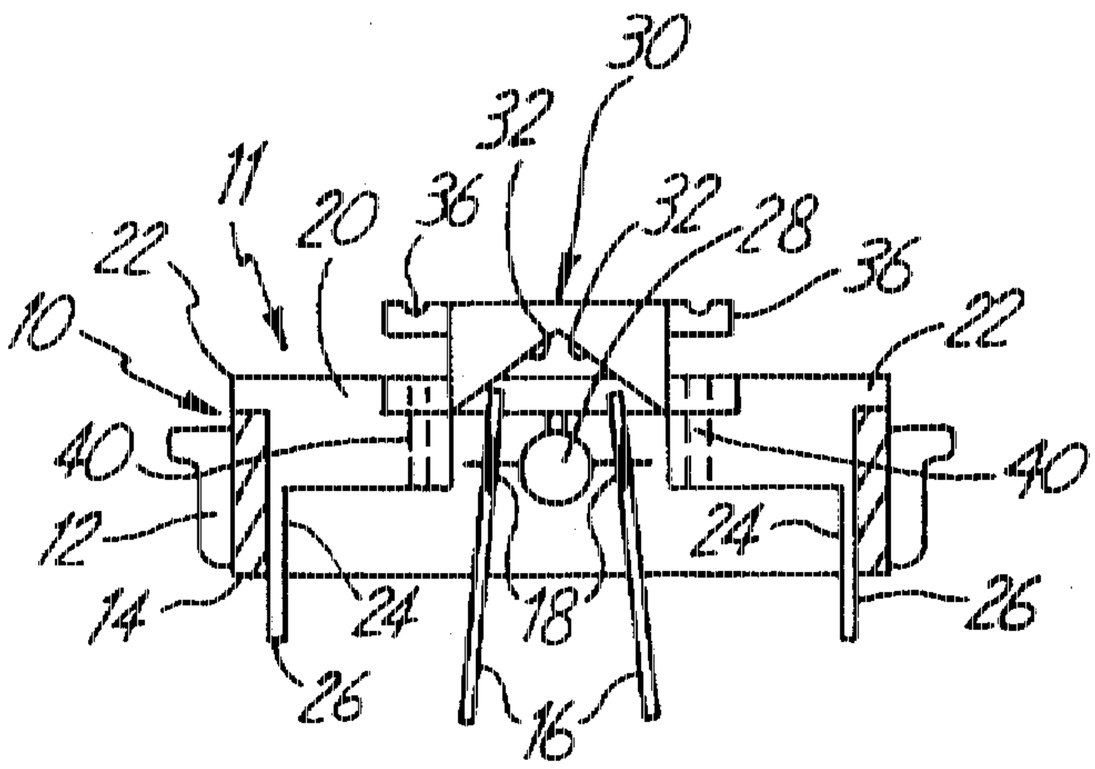


Fig. 1A

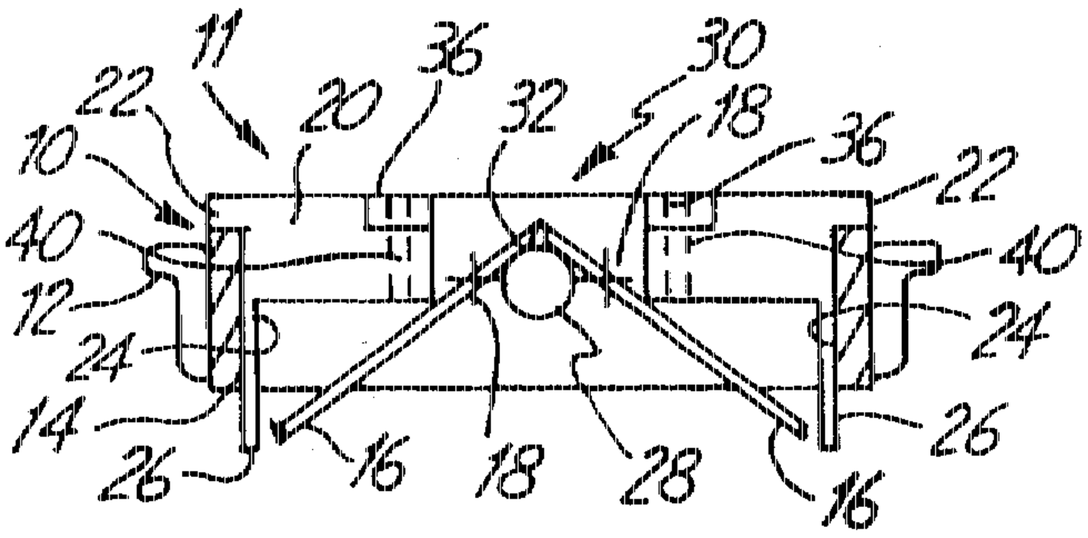


Fig. 1B

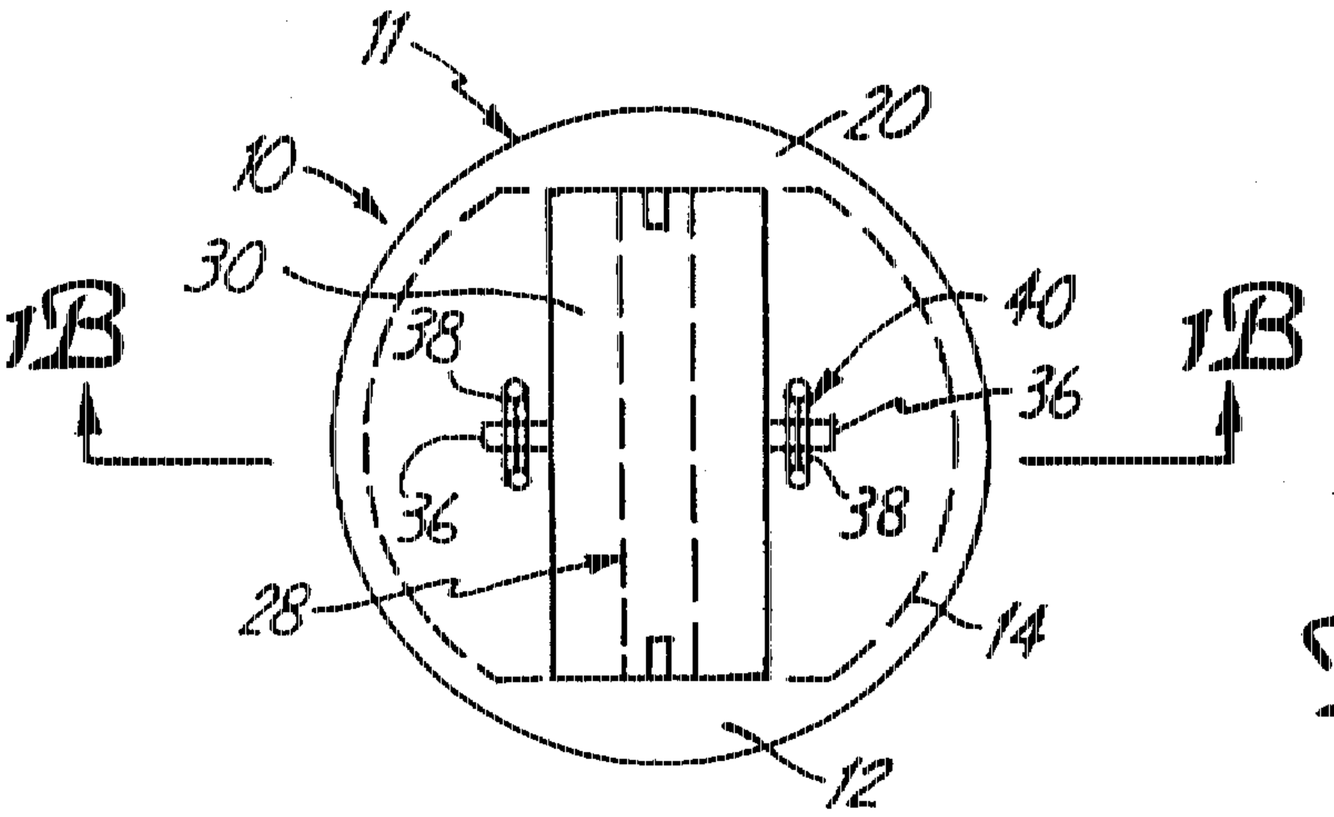


Fig. 1C

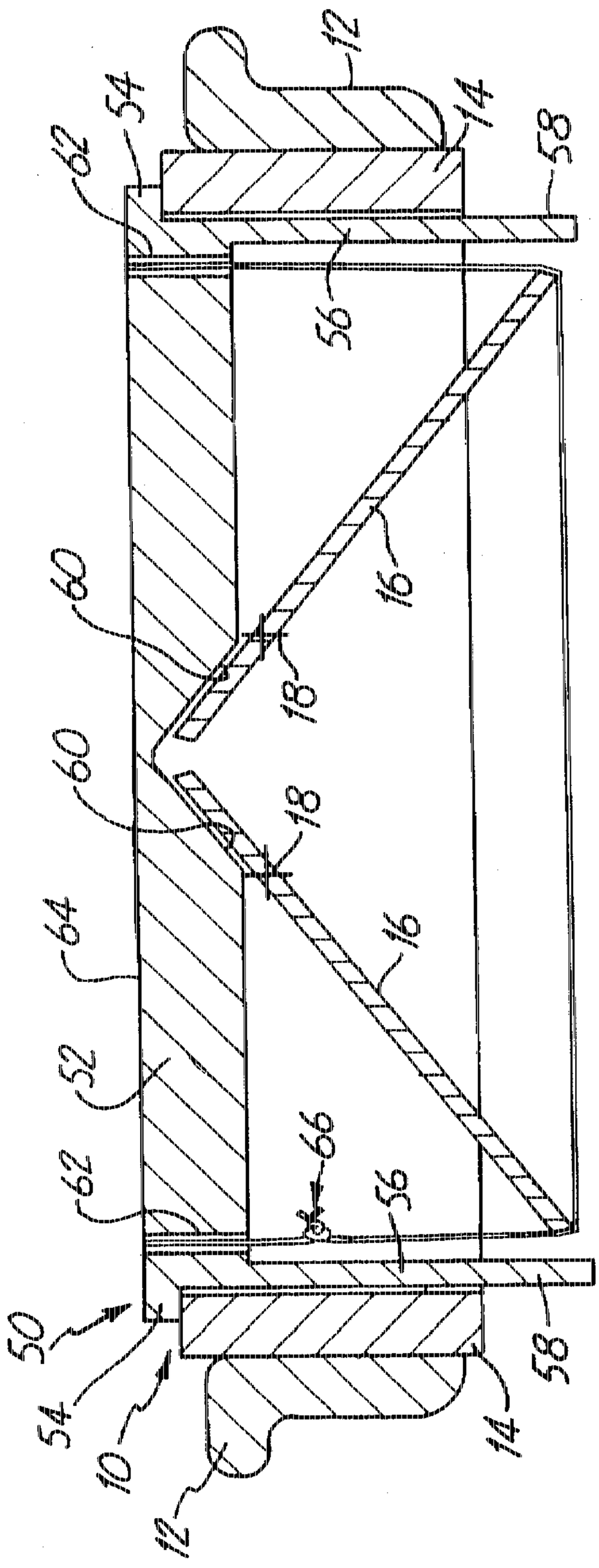


Fig. 2

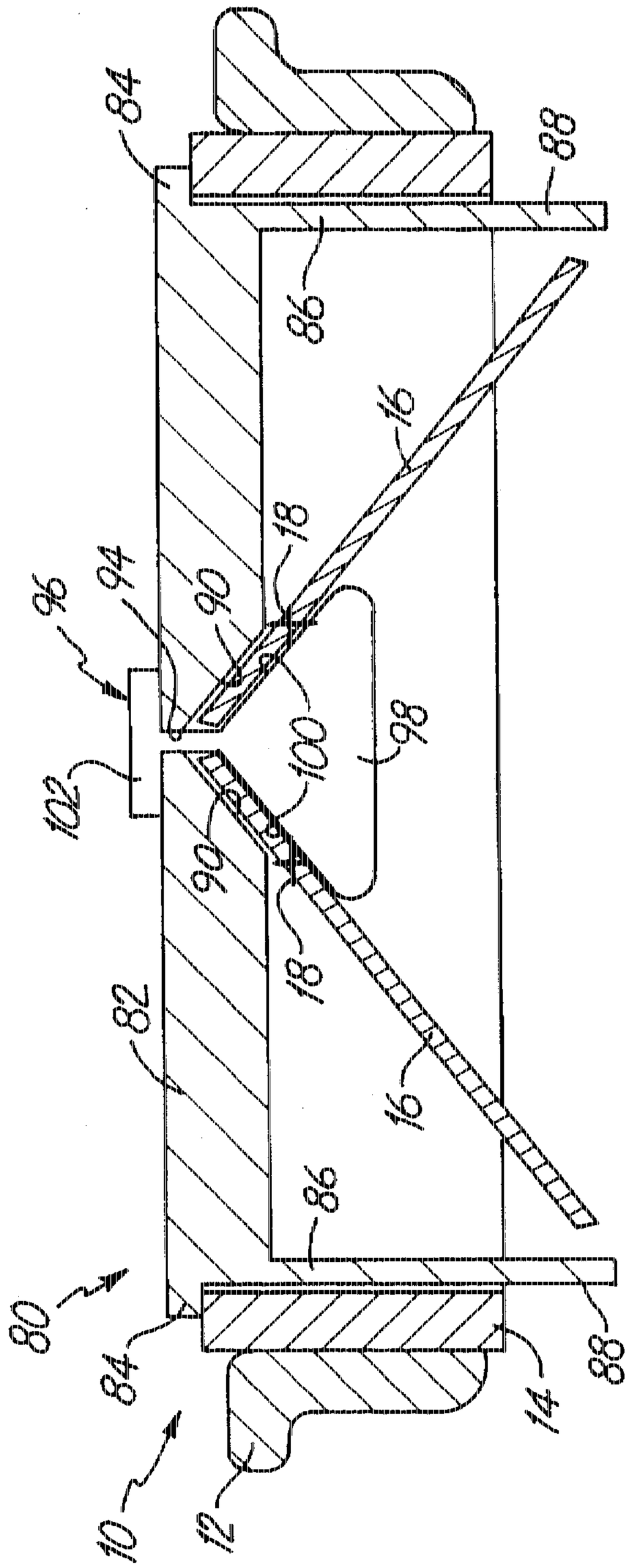
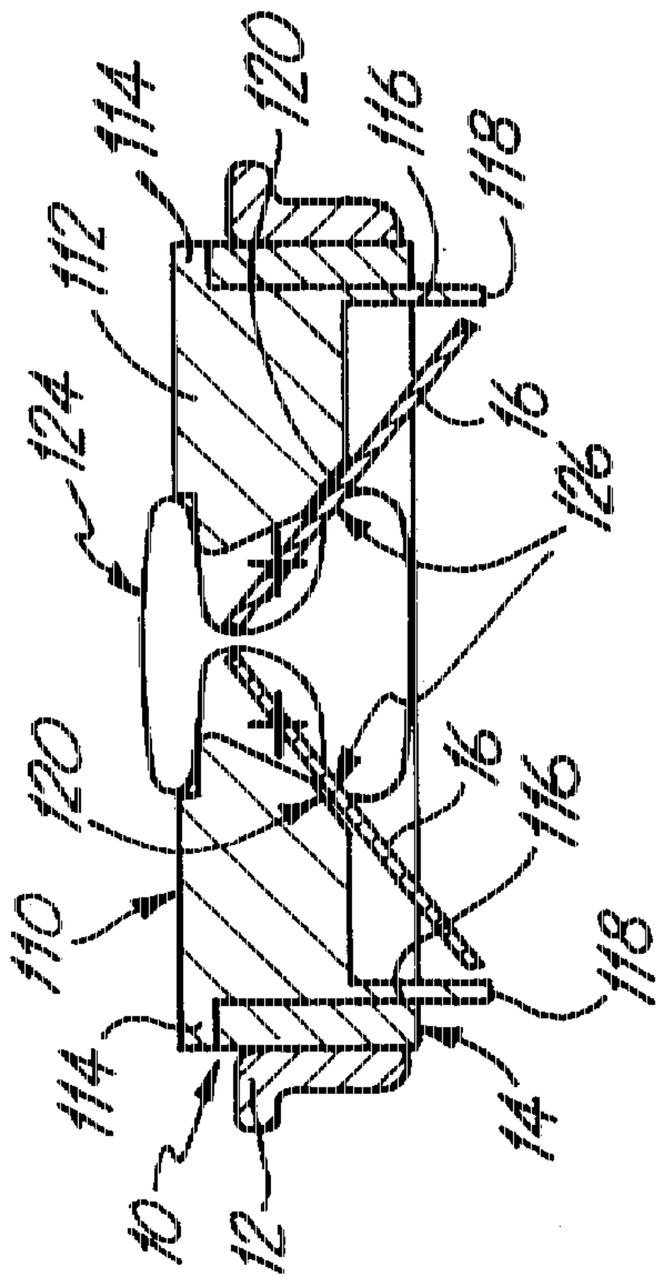


Fig. 2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10
12

Fig. 4B

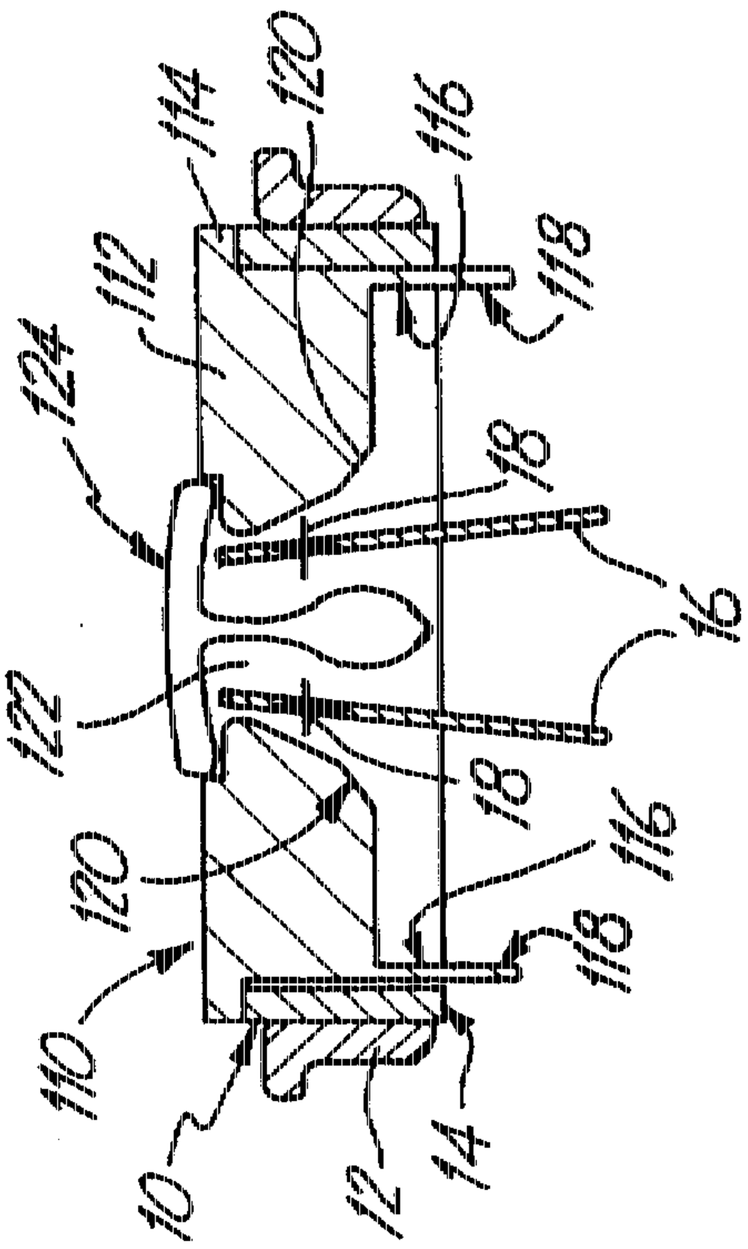
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Fig. 4A

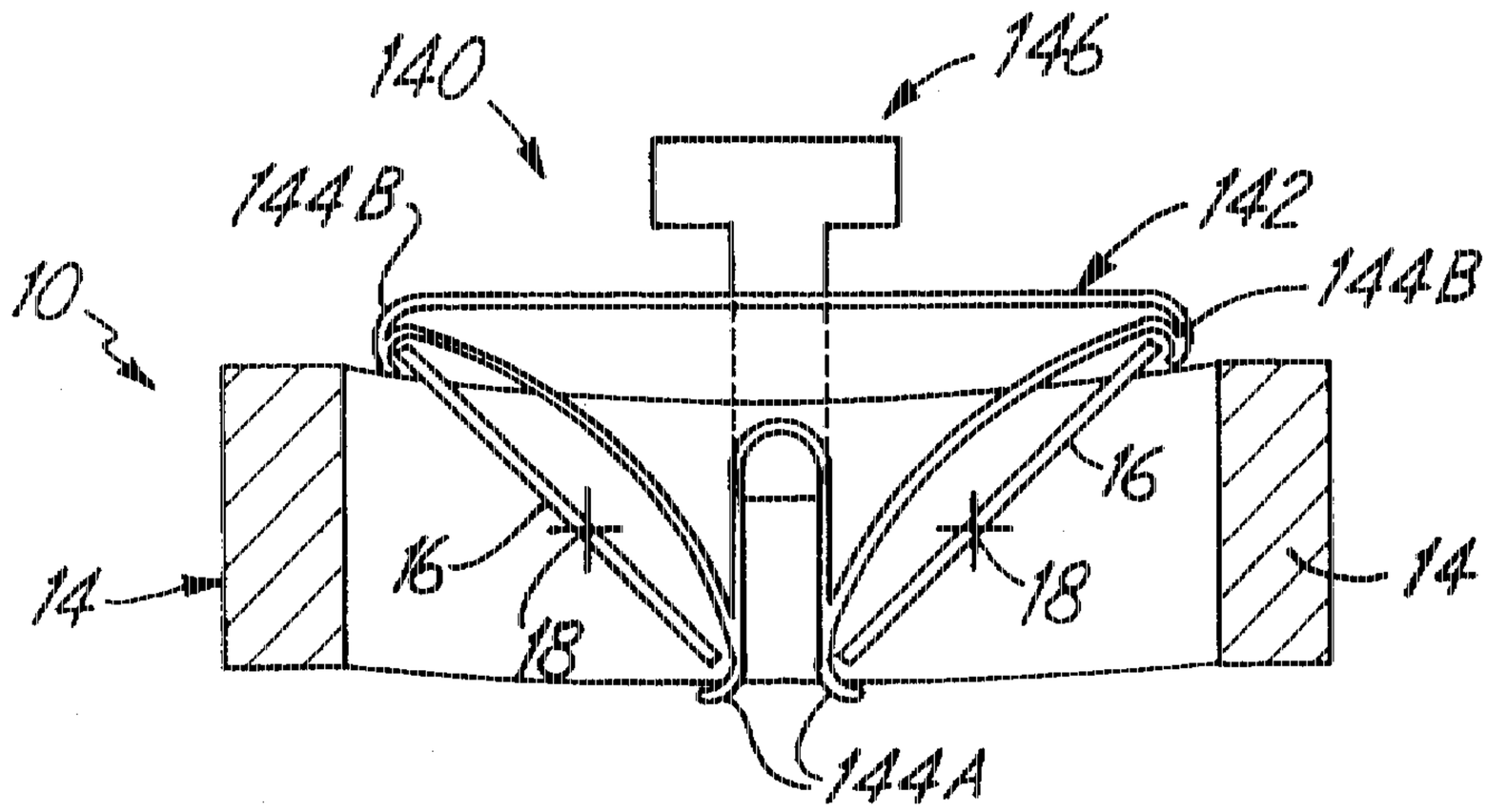
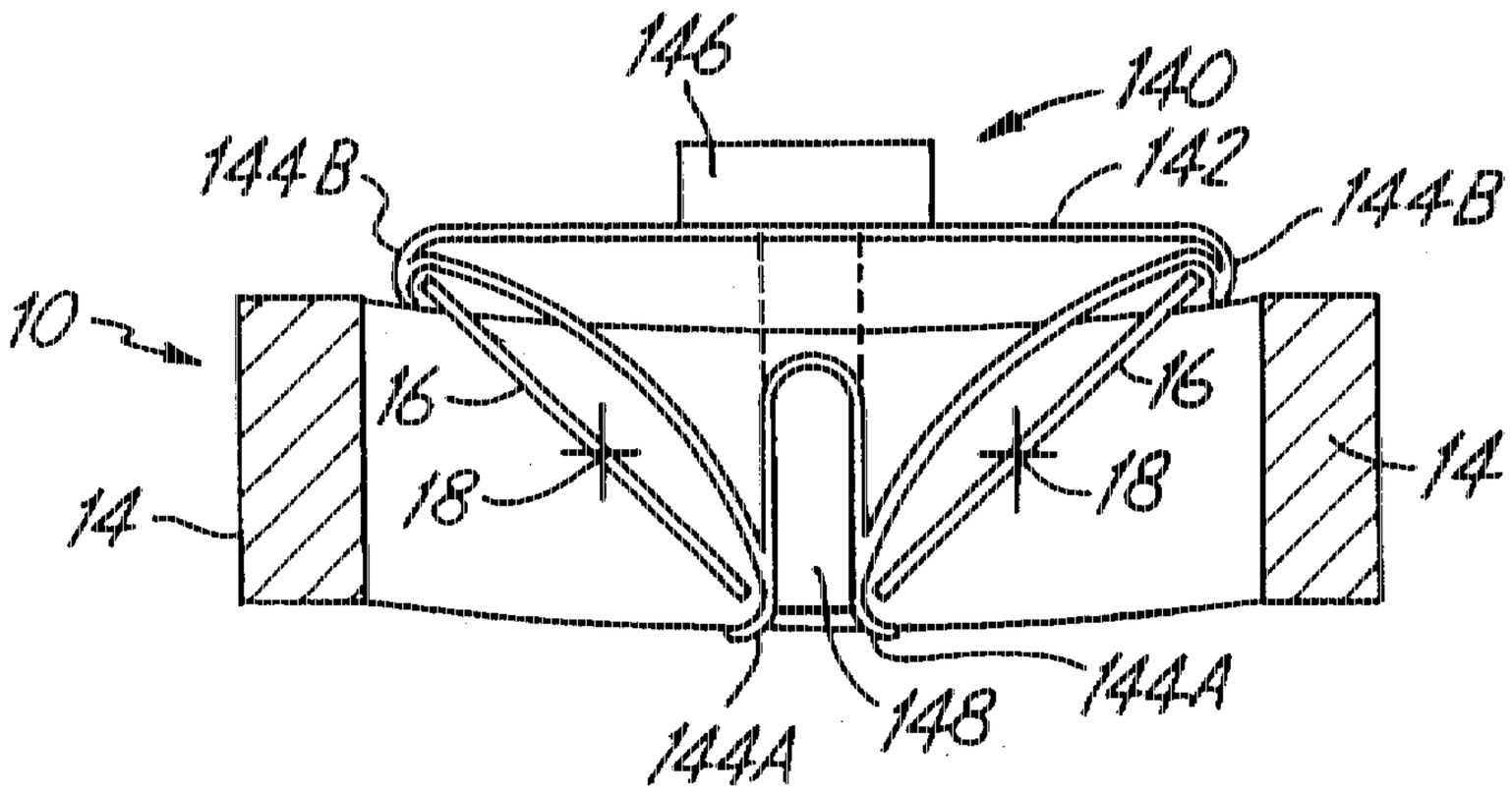

140
146
142
144B
10
16
18
14
144A

Fig. 5-A


146
140
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144B
10
16
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144A

Fig. 5B

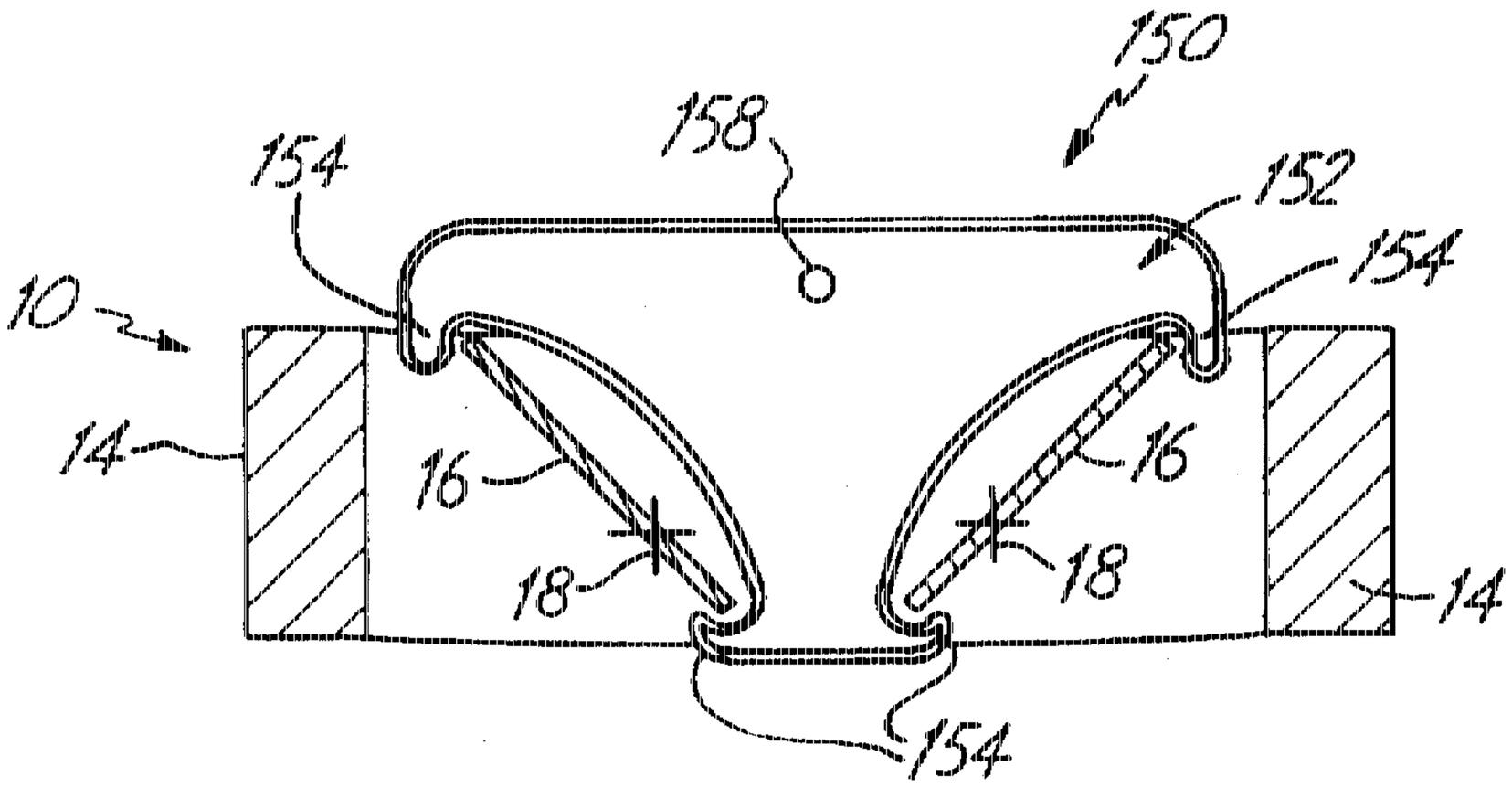
150
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Fig. 6A

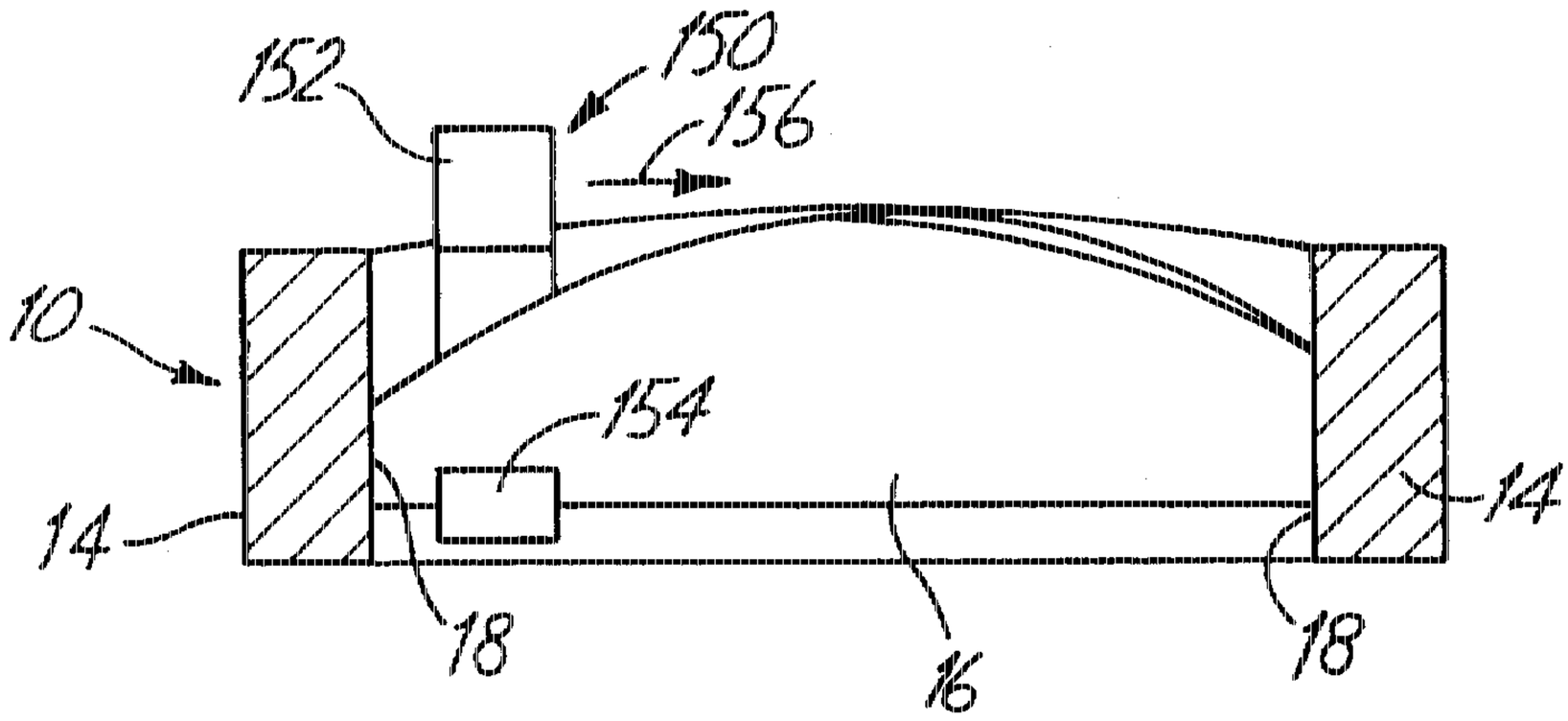
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Fig. 6B

APPARATUS FOR ATTACHMENT OF HEART VALVE HOLDER TO HEART VALVE PROSTHESIS

The present invention relates to devices for implanting heart prostheses. More specifically, the invention relates to attachment of a heart valve holder to a heart valve prosthesis.

BACKGROUND OF THE INVENTION

Holders for holding heart valve prostheses during implantation are known. They are used for positioning, holding, supporting and presenting the valve during surgery. U.S. Pat. No. 3,828,787, issued Aug. 13, 1974, to Anderson et al., entitled COLLET FOR HOLDING HEART VALVE, shows a heart valve holder carried on a distal end of an elongated handle. U.S. Pat. No. 4,932,965, issued Jun. 12, 1990, to Phillips, entitled ARTIFICIAL VALVE, AND NEEDLE AND SUTURE HOLDER AND METHOD OF USING SAME, shows another heart valve holder in which the valve is held against distal ends of a pair of elongated legs during implantation.

Typically, heart valve replacement surgery is an involved procedure in which a sternotomy or thoracotomy is performed and the chest cavity of the patient must be widely opened to provide access to the patient's heart. This provides a surgeon with direct, unobstructed access to the heart. However, this procedure requires a prolonged period to recover from the trauma suffered to the upper torso.

Recently, a procedure has been developed wherein open heart surgery is performed through trocars placed in small incisions between ribs of the patient. This is described in International Publication No. WO 95/15715, entitled DEVICES AND METHODS FOR INTRACARDIAC PROCEDURES; U.S. Pat. No. 5,433,700, issued Jul. 18, 1995, to Peters, entitled METHOD FOR INTRALUMINALLY INDUCING CARDIOPLEGIC ARREST AND CATHETER FOR USE THEREIN; U.S. Pat. No. 5,425,705, issued Jun. 20, 1995, to Evard et al., entitled THORACOSCOPIC DEVICES AND METHODS FOR ARRESTING THE HEART; and International Publication No. WO 94/18881, entitled METHOD FOR PERFORMING THORASCOPIC CARDIAC BYPASS PROCEDURES. In this procedure, elongated tools are used to operate on the heart through the trocars. As discussed in Publication No. WO 95/15715, this procedure can be used during heart valve replacement. When a heart valve prosthesis is inserted through a trocar, extreme care has to be taken for protecting the occluders in the valve, and once inserted, it becomes desirable to change the orientation of the valve prior to implantation to simplify the suturing of the heart valve prosthesis in place.

The trocar results in minimal rib spreading and does not involve the significant chest trauma associated with traditional open heart surgery. One advantage of this procedure is that the recovery period can be reduced significantly. Unfortunately, mechanical heart valves and the associated assembly used for implantation are large relative to the intercostal space between the ribs and are difficult to fit therethrough. Further, the heart valve holder must be securely attached to the heart valve prosthesis and yet be easily removed once the valve has been attached to the heart tissue annulus.

SUMMARY OF THE INVENTION

A device for engaging a heart valve prosthesis during implantation includes a mechanism for attaching the device

to the heart valve prosthesis. The heart valve prosthesis includes a circular valve body having an annulus with a substantially annular aperture therein. At least one movable occluder is carried in the annulus and is movable between an open position and a closed position. The attachment mechanism includes a member which engages to the occluder(s), thereby affixing the device to the valve prosthesis at the occluder(s). The member is selectively removable from the occluder(s) thereby releasing the device from the occluder (s). In one embodiment, an elongated handle couples to the device and extends away from the device in a plane generally parallel with a plane formed by the annulus of the heart valve prosthesis.

In one embodiment, the attachment mechanism is disengaged by withdrawing the attachment mechanism from the occluder. This may be by directly pulling on the attachment mechanism or by actuating a withdrawal apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a cross sectional view of a heart valve prosthesis adjacent a holder in accordance with one embodiment.

FIG. 1B is a cross sectional view of the holder and heart valve prosthesis of FIG. 1A showing a holder engaged with the heart valve prosthesis.

FIG. 1C is a top plan view of the holder of FIG. 1B in the engaged position.

FIG. 2 is a cross sectional view of a heart valve holder in accordance with another embodiment engaged with a heart valve prosthesis.

FIG. 3 is a cross sectional view of a heart valve holder in accordance with another embodiment engaged with a heart valve prosthesis.

FIG. 4A is a cross sectional view showing a holder in accordance with another embodiment adjacent a heart valve prosthesis.

FIG. 4B is a cross sectional view of a holder of FIG. 4A engaged with the heart valve prosthesis.

FIG. 5A is a cross sectional view of a holder in accordance with another embodiment adjacent a heart valve prosthesis.

FIG. 5B is a cross sectional view of the holder of FIG. 5A engaged with the heart valve prosthesis.

FIG. 6A is a cross sectional view of a holder in accordance with another embodiment engaged with the heart valve prosthesis.

FIG. 6B is a cross sectional view of the holder and heart valve prosthesis of FIG. 6A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention relates to attachment of a prosthetic heart valve holder to a heart valve prosthesis. The holder is used to position the heart valve prosthesis during implantation. In one embodiment, this implantation is through minimally invasive surgery such as when performed through a small trocar. The holder and valve are carried at the distal end of a handle which extends perpendicular to the axis of the valve annulus during insertion through the trocar. Reference is made to copending application Ser. No. 08/526,530 filed on even date herewith entitled LOW PROFILE MANIPULATORS FOR HEART VALVE PROSTHESES. For purposes of this description of the invention, the holder and attachment mechanism will be described generally with regard to its use. The holder and attachment mechanism may be used

with any appropriate heart valve prosthesis including heart valve prostheses which are available from St. Jude Medical, Inc., of St. Paul, Minn.; Baxter Healthcare Corp., Edwards CVS Div., Irvine, Calif.; Medtronic, Inc., Minneapolis, Minn.; Shiley, Inc., Irving, Calif.; Omniscience Medical Inc., Grove Heights, Minn.; Carbomedics, Inc., Austin, Tex.; and Sorin Biomedica, Saluggia, Italy. In general, heart valve prostheses depicted herein are shown in a generic form and the scope of the present invention is intended to cover variations required to adapt the holder and attachment mechanism to different heart valve prostheses.

FIG. 1A is a cross sectional view of heart valve prosthesis **10** and heart valve holder **11** in accordance with one embodiment of the present invention. Prosthesis **10** includes suture cuff **12** and heart valve prosthesis body **14**. Body **14** forms an annulus for allowing blood flow therethrough. Occluders **16** are positioned in the heart valve prosthesis body **14** and are movable between an open position as shown in FIG. **1**A to a closed position as shown in FIG. 1B. Occluder(s) **16** rotate about pivots **18**. Although the particular heart valve prosthesis **10** has been shown in accordance with one embodiment, other heart valves may also be used with the present invention. For example, the heart valve prosthesis may include different numbers of occluders including a single occluder, may have a different orifice or annulus shape, or the occluders may operate in accordance with a different mechanism.

Heart valve prosthesis holder **11** includes a top member **20** having lip portion **22** which engages the top rim of heart valve prosthesis body **14**. Holder **11** includes interior extensions **24** which provides a surface adapted to engage the interior surface of heart valve prosthesis body **14**. Distal ends **26** protrude beyond the bottom rim of heart valve prosthesis body **14** and occluder(s) **16**. Holder **11** includes capture rod **28** which is positioned between occluder(s) **16**, and in the embodiment of FIGS. **1**A–1C, is aligned between pivots **18**. In FIG. **1**A, a capture block **30** of holder **11** is shown in an open or released position. Capture block **30** includes occluder engaging surfaces **32** adapted to conform to the surfaces of occluders **16** and maintain occluders **16** in the partially closed position shown in FIG. 1B. FIG. **1**B shows capture block **30** moved in a closed position downward relative to top member **20** such that occluder engaging surfaces **32** engage occluders **16** in the partially closed position. This causes the occluder(s) **16** to be captured between capture rod **28** and occluder engaging surfaces **32** of capture block **30**. Capture block **30** includes suture flanges **36**.

FIG. 1C is a top plan view of holder **11** showing sutures **38** which secure capture block **30** to top member **20** by extending around suture lips **36** through suture holes **40**.

In operation, heart valve prosthesis **10** is held by heart valve holder **11** as shown in FIGS. 1B and 1C at occluders **16**. Occluders **16** are maintained in a partially or fully closed position and are protected from damage by distal portions **26** or heart valve prosthesis body **14** during implantation. In this position, a surgeon attaches heart valve prosthesis **10** to the tissue annulus formed by excision of the natural heart valve from a patient. Suture cuff **12** is sutured to the heart tissue annulus by techniques known in the art. Following attachment of heart valve **10** to the tissue annulus, heart valve holder **11** may be removed by cutting sutures **38** and moving capture block **30** to the open position shown in FIG. **1**A. Removal and manipulation of holder **11** may be with an elongated handle (not shown). This frees occluder(s) **16** such that holder **11** may be removed from prosthesis **10**.

FIG. **2** is a cross sectional view of heart valve holder **50** in accordance with another embodiment engaged with heart valve prosthesis **10**. Heart valve holder **50** includes top member **52** having lip portion **54** adapted for engagement with the top rim of heart valve prosthesis body **14**. Holder **50** includes interior extensions **56** which conform to the interior surface of heart valve prosthesis body **14** and distal extensions **58** which extend beyond the lower rim of heart valve prosthesis body **14** and occluder(s) **16**. Top member **52** includes occluder conforming surfaces **60** which are adapted to conform to occluders **16** when holder **50** is engaged with heart valve prosthesis **10** as shown in FIG. **2**. Top member **52** includes suture holes **62** adapted for receiving a suture **64**. Suture **64** extends around top member **52**, through suture holes **62** and around occluders **16**, thereby securing holder **50** to heart valve prosthesis **10**. Suture **64** is secured with knot **66**. Holder **50** is held against prosthesis **10** at occluder conforming surfaces **60** and lip portion **54** due to the pressure applied on occluders **16** by suture **64**. Distal extensions **58** protect occluders **16** from damage during implantation. Following implantation of heart valve prosthesis **10**, holder **50** may be removed by cutting suture **64** and disengaging holder **50** from heart valve prosthesis **10**. Although only a single suture **64** is shown, multiple sutures may also be used.

FIG. **3** is a cross sectional view of heart valve prosthesis holder **80** in accordance with another embodiment engaged with heart valve prosthesis. Holder **80** includes top member **82** and lip portion **84**. An interior extension **86** generally conforms to the interior surface of heart valve prosthesis body **14**. Distal extensions **88** extend beyond the bottom of heart valve prosthesis body **14**. Top member **82** includes occluder conforming surfaces **90** adapted to conform to occluders **16**, as shown in FIG. **3**. Top member **82** includes opening **94** adapted to receive locking key **96**. Locking key **96** includes interior locking portion or member **98** having occluder engaging surfaces **100** and handle **102**.

Holder **80** is held to prosthesis **10** between conforming surfaces **90** of top member **82** and engaging surfaces **100** of locking key **96**. Following insertion and attachment of heart valve prosthesis **10** to the heart tissue annulus of a patient, holder **80** is removed by rotating locking key **96** ninety degrees about the axis of prosthesis **10** such that occluders **16** are freed from occluder engaging surfaces **100**. In this position, occluder(s) **16** are disengaged. Thus, prosthesis holder **80** may be removed from valve prosthesis **10**. Alternatively, member **98** may be removed from valve holder **80** through opening **94** in top member **82**. Holder **80** may then be removed from prosthesis **10**. Distal extensions **88** protect occluders **16** during implantation. Variations on this embodiment include changing the position or length of the engaging surface **100** and conforming surface **90**. Another variation would be insertion of a key member(s) adjacent to, but not between, occluder(s) **16**, which engage distal ends of occluder(s) **16** such that interior extension **86** would not be required.

Alternatively, holder **80** may be held to prosthesis **10** between lip portion **84** and engaging surface **100** of locking key **96**.

FIG. **4**A is a cross sectional view of a heart valve prosthesis holder **110** in accordance with another embodiment. Holder **110** includes top member **112** having lip portion **114** adapted for engaging heart valve prosthesis body **14**. Interior extensions **116** conform to the interior surface of heart valve prosthesis body **14** and connect to distal extensions **118** which extend beyond the bottom rim of heart valve prosthesis body **14**. Top member **112** includes occluder conforming surfaces **120** adapted for engaging occluders **16**. Opening **122** in top member **112** receives

inflatable element **124**. Inflatable element **124** is shown in a deflated condition in FIG. **4**A and in an inflated condition in FIG. **4**B. In an inflated condition, inflatable element **124** provides occluder engaging surfaces **126** such that occluders **16** are captured between engaging surfaces **126** and conforming **120**, thereby securing holder **110** to heart valve prosthesis **10**. Support is also provided by lip portion **114**. Distal extensions **118** protect occluders **16** during implantation. Following attachment of heart valve prosthesis **10** to the heart tissue annulus, holder **110** is removed by deflating inflatable element **124** such that holder **110** may be lifted from prosthesis **10**. An elongated control coupling may be provided to element **124** to selectively, remotely deflate element **124**.

Alternatively, valve prosthesis **10** is captured between engaging surface **126** and lip portion **114** of holder body **110**.

FIG. **5**A is a cross sectional view of a holder **140** in accordance with another embodiment adjacent heart valve prosthesis **10**. Prosthesis **10** is shown in simplified form having body **14**, occluders **16** and pivots **18**. Holder **140** includes gripper **142** having attachment mechanisms **144**A and **144**B which extend around edges of occluders **16**. A plunger **146** extends through an opening in gripper **142** and is shown in a withdrawn position in FIG. **5**A.

In FIG. **5**B, tip portion **148** of plunger **146** causes attachment mechanisms **144**A to spread apart thereby locking gripper **142** to occluders **16**. In the embodiment of holder **140** in FIGS. **5**A and **5**B, a control coupling mechanism (not shown) may be provided to control operation of plunger **146** from a remote location. Similarly, such a control mechanism may be used in the other embodiments set forth herein.

FIG. **6**A is a cross sectional view of holder **150** in accordance with another embodiment engaged with heart valve prosthesis **10**. Holder **150** in FIG. **6**A is similar to holder **140** of FIGS. **5**A and **5**B. Holder **150** includes body **152** having engagement mechanisms **154** which engaged edges of occluders **16**.

FIG. **6**B is a cross sectional view of holder **150** in heart valve prosthesis **10**. FIG. **6**B is a cross sectional view with valve **10** in holder **150** rotated ninety degrees about the axis of valve **10** in FIG. **6**A. FIG. **6**B shows holder **150** offset from the center axis of valve **10** such that holder **150** is disengaged from valve **10**. Holder **150** may be positioned to engage occluders **16** by moving holder **150** in the direction indicated by arrow **156** in FIG. **6**B. Holder **150** includes suture hole **158** shown in FIG. **6**A which is capable of receiving a suture (not shown) to secure holder **150** in an engaged position with occluders **16**.

As used herein, attachment mechanism is used to mean a mechanism for attaching to the occluder. The preferred embodiments set forth a number of attachment mechanisms. However, the term "attachment mechanism" is intended to describe any other mechanism for attaching a valve to an occluder which is within the scope of the invention.

It should be understood that the present invention extends to any variation or embodiment which would be apparent to those skilled in the art. The concepts set forth herein are applicable to any appropriate valve configuration for both aortic and mitral implantation.

Typically, the holders described herein are attached to an elongated handle such that a surgeon may manipulate the heart valve using the proximal end of the handle during implantation.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

What is claimed is:

1. An apparatus for holding a heart valve prosthesis and providing a low profile during implantation, the heart valve prosthesis including a heart valve prosthesis body and a movable occluder having a first occluder surface and a second occluder surface opposite the first occluder surface, the apparatus comprising:

a top member sized to fit proximate an annulus of the heart valve prosthesis;

a lip portion coupled to the top member adapted for abutting the annulus of the heart valve prosthesis;

an interior extension coupled to the top member extending through heart valve prosthesis body and generally conforming to an interior portion of the prosthesis body;

a distal extension coupled to the interior extension extending beyond the heart valve prosthesis body opposite the top member to protect the movable occluder;

a conforming surface in the top member shaped to conform to the first occluder surface to maintain the first occluder surface in a substantially closed position when the top member and lip portion engage the prosthesis body; and

a suture extending around the top member and adapted to extend around the movable occluder, thereby coupling the top member to the heart valve prosthesis body and the conforming surface to the fist occluder surface and maintaining the movable occluder in the substantially closed position whereby the occluder is protected from damage by the heart valve prosthesis body and the distal extension.

2. The apparatus of claim **1** including a second conforming surface adapted to conform to a first surface of a second movable occluder of the heart valve prosthesis to maintain the second movable occluder in a substantially closed position.

3. The apparatus of claim **1** wherein the top member includes a suture hole formed therein for receiving the suture.

* * * * *